BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM 37.86.1101 and 37.86.1105 pertaining to Medicaid reimbursement for dispensing fees and outpatient compound prescriptions	)))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Interested Persons

1. On November 14, 2007, at 3:30 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room, 2401 Colonial Drive, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process (including reasonable accommodations at the hearing site) or who need an alternative accessible format of this notice. If you need an accommodation, contact the department no later than 5:00 p.m. on November 5, 2007. Please contact Rhonda Lesofski, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena MT 59604-4210; telephone (406)444-4094; fax (406)444-1970; e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows. New matter is underlined. Matter to be deleted is interlined.

37.86.1101 OUTPATIENT DRUGS, DEFINITIONS (1) through (2) remain the same.

(3) "Maximum allowable cost (MAC)" means the upper limit the department will pay for multi-source drugs. In order to establish base prices for calculating the maximum allowable cost, the department ~~hereby~~ adopts and incorporates by reference the methodology for limits of payment set forth in ~~42 CFR 447.331 and 447.332 (1996)~~ 42 CFR 447.512 and 447.514 (2007). The maximum allowable cost for multi-source drugs will not exceed the total of the dispensing fee established by the department and an amount that is equal to the price established under the methodology set forth in ~~42 CFR 447.331 and 447.332~~ 42 CFR 447.512 and 447.514 (2007) ~~for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules or, in the case of liquids, the commonly listed size. If the drug is not commonly available in quantities of 100, the package size commonly listed will be the accepted quantity~~. A copy of the above-cited regulations may be obtained from the Department of Public Health and Human Services, Health Policy and Services Division, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(4) remains the same.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-2-201, 53-6-101, 53-6-111, 53-6-113, MCA

37.86.1105 OUTPATIENT DRUGS, REIMBURSEMENT (1) Drugs will be paid for on the basis of the Montana "estimated acquisition cost" or the "maximum allowable cost", plus a dispensing fee established by the department, or the provider's "usual and customary charge", whichever is lower; except that the "maximum allowable cost" limitation shall not apply in those cases where a physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the Medicaid program certifies in their own handwriting that in their medical ~~judgement~~ judgment a specific brand name drug is medically necessary for a particular patient. An example of an acceptable certification would be the notation "brand necessary" or "brand required". A check-off box on a form or a rubber stamp is not acceptable.

(2) The dispensing fee for filling prescriptions shall be determined for each pharmacy provider annually.

(a) The dispensing fee is based on the pharmacy's average cost of filling prescriptions and whether the pharmacy dispenses a generic, preferred drug list (PDL) or non-PDL drug. The average cost of filling a prescription will be based on the direct and indirect costs that can be allocated to the cost of the prescription department and that of filling a prescription, as determined from the Montana Dispensing Fee Questionnaire. Considerations in determining the dispensing fee include but are not limited to: prescription volume, overhead costs, pharmacy personnel wages, and special packaging. A provider's failure to submit~~, upon request, the~~ a properly completed dispensing fee questionnaire ~~properly completed upon request~~ will result in the assignment of the minimum dispensing fee offered. A copy of the Montana Dispensing Fee Questionnaire is available upon request from the department.

(b) The dispensing fees assigned for in-state providers shall range between a minimum of $2.00, a $5.50 dispensing fee for non-PDL brand medications and new in-state providers and a maximum of $10.00 for PDL and generic medications ~~and a maximum of $4.70~~.

(c) and (d) remain the same.

(3) In-state pharmacy providers that are new to the Montana Medicaid program will be assigned an interim ~~$3.50~~ $5.50 dispensing fee until a dispensing fee questionnaire, as provided in (2), can be completed for six months of operation. At that time, a new dispensing fee will be assigned which will be the lower of the dispensing fee calculated ~~in accordance with (2) for the pharmacy or the $4.70 dispensing fee~~ as provided in (2)(b). Failure to comply with the six months dispensing fee questionnaire requirement will result in assignment of a dispensing fee of $2.00.

~~(4) "Unit dose" prescriptions will be paid by a separate dispensing fee of $0.75. This "unit dose" dispensing fee will offset the additional cost of packaging supplies and materials which are directly related to filling "unit dose" prescriptions by the individual pharmacy and is in addition to the regular dispensing fee allowed. Only one unit dose dispensing fee will be allowed each month for each prescribed~~

~~medication. A dispensing fee will not be paid for a unit dose prescription packaged by the drug manufacturer.~~

(4) The department shall reimburse pharmacies for compounding drugs only if the client's drug therapy needs cannot be met by commercially available dosage strengths and/or forms of the therapy.

(a) Prescription claims for compound drugs shall be billed and reimbursed using the National Drug Code (NDC) number and quantity for each compensable ingredient in the compound.

(b) No more than 25 ingredients may be reimbursed in any compound.

(c) Reimbursement for each drug component shall be determined in accordance with ARM 37.86.1101.

(d) Prior authorization requirements for individual components of a compound must be met for reimbursement purposes.

(e) Prior authorization shall be required to be reimbursed for a dispensing fee over $12.50.

(f) The dispensing fee for each compounded drug shall be $12.50, $17.50, or $22.50 based on the level of effort required by the pharmacist.

(g) The department does not consider reconstitution to be compounding.

(h) The department will publish guidelines for billing the different level of effort fees.

(5) through (7) remain the same.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, 53-6-113, 53-6-141, MCA

4. The department is proposing a change to the reimbursement methodology for pharmacy providers based the direction provided in the Deficit Reduction Act of 2005 (Public Law No. 109-171) and the proposed federal regulations to implement it (42 CFR Chapter IV). These changes are necessary because the existing rules are inconsistent with the reimbursement methodology proposed by the Centers for Medicare and Medicaid Services (CMS). Specifically, the proposed amendments to 42 CFR 447 change the methodology by which the department calculates the federal upper payment limit. The portions of the rules to be deleted are inconsistent with the new methodology. The department has made every effort to anticipate the consequences of the new federal rules in determining the changes needed to adjust to the new reimbursement methodology. The department analyzed data provided by CMS and has determined that, overall, there will be up to a 29% decrease in reimbursement from Medicaid for generic drugs. Reimbursement for brand name products will remain about the same.

The department has the option of considering other pricing methodologies as long the department meets the Federal Maximum Allowable Cost (FMAC) provisions. That is, in the aggregate, the department must not pay more for those drugs that have an FMAC. The department has explored other pricing methodologies, such as Retail Acquisition Cost (RAC), and Wholesale Acquisition Cost (WAC). At this time, the department has chosen to continue the use of FMAC to ensure compliance with the reporting and payment requirements. Many manufacturers do not report RAC or

WAC, and the administrative burden of the coding and researching these pricing methodologies would be prohibitive at this time.

The department is proposing a minor grammatical change to ARM 37.86.1105(2)(a). This change is intended to make the sentence easier to read and understand. No substantive change is intended.

Dispensing Fees

The department is proposing changes to the pharmacy dispensing fee rule to reflect results from a state-wide Montana Medicaid cost of dispensing survey, as well as to address the redefinition "dispensing fee" in the Deficit Reduction Act of 2005 (DRA). The new definition of dispensing fee as provided in the DRA includes specialty packaging as a consideration in the overall dispensing fee. The department conducted a dispensing fee survey of in-state providers in February to April of 2007 to determine the actual cost for a Montana Medicaid pharmacy provider to dispense a drug. 99% of Montana Medicaid pharmacies responded. The department found that Montana pharmacy providers have seen an increase in the cost of dispensing medications since the last change in pharmacy dispensing fees in 2002. The dispensing fee currently allowed for Montana Medicaid is $4.86. The survey results showed that an average cost to dispense a drug for Montana pharmacies is $10.74. The range of costs to dispense, within one standard deviation, was $6.16 to $15.26. Excluding those pharmacies whose cost to dispense was outside one standard deviation, the department found the average cost to dispense was $9.93. A nationwide survey performed by Grant Thornton LLP, on behalf of the National Association for Chain Drug Stores (NACDS) found an average national cost of dispensing of $10.50 per prescription, and a Montana-specific cost of dispensing of $11.46. The NACDS survey had a significantly lower response rate (25-33% responses) than the department's survey. However, their results correlated well with the department's more complete data.

From the above analysis, the department determined that a $10.00 maximum dispensing fee was adequate reimbursement for Montana pharmacies, while still capturing some of the savings intended by the DRA. Many pharmacies will not receive the maximum dispensing fee because their overall costs to dispense were less than $10.00. Those pharmacies with a cost to dispense lower than $10.00 will receive their reported cost to dispense, as their dispensing fee. Out-of-state prescriptions would still be reimbursed with a dispensing fee of $3.50.

The department estimates that the average maximum dispensing fee will be $8.75 per prescription for in-state pharmacies overall. This figure was arrived at by creating a weighted average of known costs to dispense combined with the pharmacy volume. The department analyzed whether the $10.00 maximum dispensing fee was adequate to cover the costs of special packaging. The DRA definition of "dispensing fee" now includes special packaging, such as unit dose packages. Seventy-four pharmacies billed Montana Medicaid for the special packaging in State Fiscal Year (SFY) 2007. Three of these providers were out-of-

state. Of the 71 Montana providers, 14 would have dispensing fees less than $8.75. The prescriptions filled for these 14 pharmacies are 6.7% of the total of 56,082 prescriptions billed using a unit dose indicator. The department's conclusion is that the elimination of a separate unit dose dispensing fee will minimally impact those pharmacies providing unit dose packaging.

The department considered setting differential dispensing fees based on prescription volume, number of stores, or population dynamics. However, there was no significant difference in costs to dispense between chain pharmacies and independently owned pharmacies. Nor was there a discernable difference for a small population compared to a large population. The major cost differentials came when looking at prescription volume: smaller volume stores (less than 50,000 prescriptions yearly) generally had higher costs to dispense than high volume stores. This finding was corroborated by the NACDS survey. However, these differences were not significant enough to justify a dispensing fee differential based on store volume. These differences tend to be accounted for in the "cost to dispense" calculation. The department instead chose to increase the dispensing fee for all in-state providers to maintain a widespread provider base. The department, in setting the dispensing fees based on whether the drug is generic, preferred or nonpreferred, enforces its commitment to the dispensing of medications that represent the best value to Montana Medicaid clients and the state. To that end, the department proposes to implement a higher dispensing fee on generic and preferred drugs.

Compounded Prescriptions

The department is also proposing changes to the compounding dispensing regulations. This is necessary to ensure federal matching funds are available for compounded prescriptions paid for by Medicaid. The department until now has allowed pharmacies to bill compounds using department-assigned drug codes (00888 codes). The cost of these compounds since 2001 has been $2,852,011. The average cost of a prescription billed using these codes was $83.92. To ensure Montana Medicaid only reimburses for covered outpatient drugs as outlined in 42 USC 1396r-8, the department must reimburse for each covered drug within the compound.

In comparison, "line item" compound billing reduces the overall costs of the compounds. The department has reimbursed "line item" compounds since 2004. The department has reimbursed $2,203,349 worth of compounded prescriptions using line item billing while collecting $242,368 in rebates.

The department is aware that some components in a compound are not rebatable items. The department has chosen to create compounding fees that take into account that there are occasionally nonrebatable components in compounds and allows them as overhead in the costs of doing business as a pharmacy. The average cost for nonrebatable ingredients in compounds is $4.08. Many of the nonrebatable compound ingredients cost less than a dollar per compound. Further, many of the nonrebatable compound ingredients currently used by pharmacies have

rebatable alternatives. The department encourages providers to explore rebatable or less costly excipients.

One solution to the problem of nonreimbursable ingredients in a compound was to allow the pharmacies to bill clients for the cost of these ingredients. However, this would have shifted costs to the client in addition to their existing cost share. This cost shifting might limit access to needed prescriptions for clients.

Another alternative for compound billing would be a methodology from private insurers that pay for compounded drugs, that allow the pharmacy to bill for the highest cost ingredient, then using a multiplier for the final volume of the compound. For example, if one milliliter (ml) of a medication that costs $2.00 a unit is used in the compound, and the final volume is 25 ml, the final cost of the compound is $2.00 X 25 = $50.00. Federal rebate provisions do not allow for this methodology. The department will collect the actual number of units of a drug dispensed to report back to the manufacturer for rebate collection.

Compounding takes more time and effort by the pharmacist than a commercial prescription. By adding a "level of effort" based dispensing fee for compounding, the pharmacy is reimbursed for the time it takes to create a compound. $12.50, $17.50, and $22.50 are the level of effort costs allowed. The department anticipates that the lowest fees will be used for those compounds typically made in an outpatient pharmacy, such as "magic mouthwash", "Wilson's Solution", or mupirocin in nasal saline. Higher compounding fees will be reserved for compounds that typically require aseptic technique under a laminar flow hood, or complex ingredient manipulation. Although the concern is that pharmacies will bill only the highest dispensing fee, level of effort is easily auditable. The department will also require a prior authorization for any dispensing fee over $12.50. The Prior Authorization Unit is staffed with practicing pharmacists and can easily make such determinations. The pharmacy program will publish guidelines on proper level of effort billing to further ensure consistency in application of these rules based on common practice guidelines for time and effort required for producing compounds, and guidance from other states which have similar tiered compounding fees.

Fiscal Effects

The department estimates the proposed amendments would result in $48,991 to $111,800 in additional dispensing fees per year, based on 6,300 compounded prescriptions yearly. However, this cost is offset by the cost savings yearly due to an estimated $211,692.00 in rebate and federal matching funds not realized by allowing 00888. The result would be a net cost savings to the department of $99,892.00.

The department has the discretion to treat compounds the same as regular prescription drugs and allow the maximum regular dispensing fee, currently at $4.86. The department considered and rejected a plan to keep entire cost savings without offsetting by additional dispensing fees, as other states have elected to do. This,

however, would have discouraged pharmacies from compounding prescriptions for clients needing medication not commercially available, thus creating an access problem for Medicaid recipients.

Most Montana pharmacies are capable of submitting online claims for compounds by line item. Those pharmacies that do not have electronic billing capability may still bill compounds by line item on paper. The standard MA-5 form may be used for billing of compounds to Montana Medicaid.

The department analyzed the impact of these rules using accepted statistical practices. The department took into account the fact that all out-of-state providers would receive the same $3.50 dispensing fee they do now. The department also estimated the impact of pharmacies having a lower cost to dispense prescription drugs than the maximum, as well as looking at the impact should all in-state providers receive the maximum dispensing fee. The overall impact to the budget of these two proposed changes will result in an annual savings of $181,042.

5. The department proposes the amendments be effective January 1, 2008.

6. Interested persons may submit comments orally or in writing at the hearing. Written comments may also be submitted to Rhonda Lesofski, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 4210, Helena MT 59604-4210, no later than 5:00 p.m. on November 23, 2007. Comments may also be faxed to (406)444-1970 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

7. An electronic copy of this proposal notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of this notice conform to the official version of the notice as printed in the Montana Administrative Register, but advises all concerned persons that, in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. The web site may be unavailable at times, due to system maintenance or technical problems.

8. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

9. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

/s/ John Koch
Rule Reviewer

/s/ Joan Miles
Director, Public Health and Human Services

Certified to the Secretary of State October 15, 2007.